



Smallpox Training

ACAM2000 Transition

07 May 2008

UNCLASSIFIED





PURPOSE: To provide information on the transition to ACAM2000

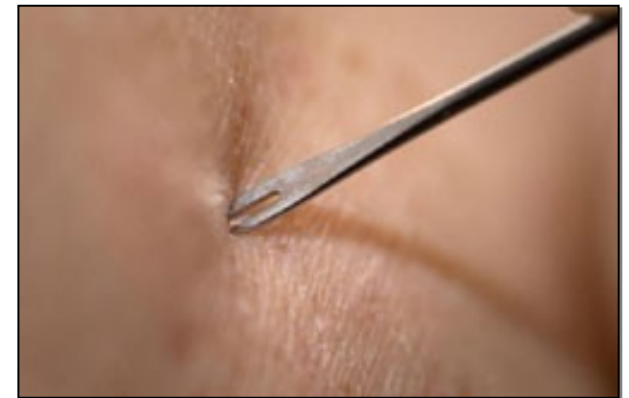
1. Clinical Issues
2. Dryvax/ACAM2000 Comparison Chart
3. Storage and Handling
4. Education Requirements
5. Immunization Record Keeping
6. Ordering Information
7. Labeling
8. Timeline





Clinical Highlights

- ACAM2000 contains a small amount of neomycin and polymyxin B
- Only use 0.3ml of diluent to reconstitute ACAM2000 vaccine
- **ALL** personnel receiving ACAM2000 (primary vaccinees and re-vaccinees) will receive 15 jabs
- Vaccine is administered by percutaneous route (scarification) using a bifurcated needle





Dryvax/ACAM2000 Comparison Chart

	DRYVAX[®] <small>(est. thru 29 Feb 08)</small>	ACAM2000[™] <small>(est. after 01 Mar 08)</small>
Manufacturer	Wyeth Lab	Acambis Inc.
Indication	For the induction of immunity against Smallpox	For the induction of immunity against Smallpox
Description	Live vaccinia virus cultured from Calf Lymph	Live vaccinia virus manufactured using cell culture technology
Pharmaceutical Properties	<ul style="list-style-type: none"> ~ The calf lymph is purified, concentrated and dried by lyophilization. During processing, polymyxin B sulfate, dihydrostreptomycin sulfate, chlortetracycline hydrochloride and neomycin sulfate are added. ~ Diluent contains: 50% glycerin and 0.25% phenol ~ 100 dose vial 	<ul style="list-style-type: none"> ~ 2% human serum albumin USP, 0.5-0.7% sodium chloride USP, 5% mannitol USP, and trace amounts of neomycin and polymyxin B ~ Diluent for ACAM2000 contains 50% (v/v) Glycerin USP, 0.25% (v/v) Phenol USP in Water for Injection USP supplied in 3mL clear glass vials containing 0.6mL of diluent ~ 100 dose vial
Medium	Calf Lymph	Vero (African Green Monkey kidney cells)
Route	Percutaneous using a bifurcated needle traditionally at an upper deltoid site (Also called scarification)	Percutaneous using a bifurcated needle traditionally at an upper deltoid site (Also called scarification)
Dosing	Primary: 3 Jabs Revaccination: 15 Jabs	Primary: 15 Jabs Revaccination: 15 Jabs
Revaccination	DoD policy requires individuals at high risk for exposure, such as laboratory personnel handling variola virus, be re-vaccinated every 3 years. Individuals deemed to be at an increased risk, such as segments of the military must be re-vaccinated every 10 years.	DoD policy requires individuals at high risk for exposure, such as laboratory personnel handling variola virus, be re-vaccinated every 3 years. Individuals deemed to be at an increased risk, such as segments of the military must be re-vaccinated every 10 years.
Storage & Handling	<ul style="list-style-type: none"> ~ Dryvax is shipped and stored at 2-8°C or 36-46°F ~ Discard vaccine 90 days after reconstitution ~ Expiration date subject to extensions 	<ul style="list-style-type: none"> ~ Un-reconstituted ACAM2000 vaccine is shipped and stored at 2-8°C (36-46°F) ~ Un-reconstituted ACAM2000 vaccine should not be exposed to room temperature (23-27°C, 73-81°F) for more than 48 hours ~ After reconstitution, ACAM 2000 vaccine may be administered within 6 to 8 hours at room temperature (20-25°C, 68-77°F) ~ Vaccine must be discarded as a bio-hazardous material 30 days after reconstitution ~ Gloves should be worn when reconstituting or administering ACAM2000 vaccine ~ Expiration dates will not be extended
Required Educational Material	DoD Smallpox individual information trifold brochure	DoD Smallpox individual information trifold brochure AND <i>Medication Guide</i>

Military Vaccine Agency

www.vaccines.mil

(877) GET-VACC

11 Jan 08

www.smallpox.mil/ACAM2000



Un-reconstituted ACAM2000™

- All un-reconstituted ACAM2000 vials released from the SNS will expire in 18 months
- Un-reconstituted ACAM2000 vaccine should not be exposed to temperatures above 23-27° C (73-81° F) for more than a total of 48 hours
- ACAM2000 vaccine should be distributed and stored at 2-8 ° C (36-46 ° F)





Reconstituted ACAM2000™

- After reconstitution ACAM2000 should be stored in the refrigerator 2-8 ° C (36-46 ° F)
- Reconstituted ACAM2000 may be exposed to temperatures 20-25 ° C (68-77 ° F) for up to 8 hours (i.e. clinic shift), after which it must be discarded as biohazard waste
- Once reconstituted, ACAM2000 should be discarded as biohazardous waste after 30 days

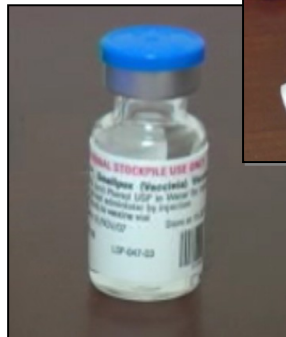




Storage and Handling (Diluent)

Diluent for ACAM2000™

- The diluent for ACAM2000 vaccine should be stored at temperatures 15-30 ° C (59-86 ° F)
- During shipment diluent can be shipped between 2-30 ° C (36-86 ° F)
- The expiration dating of diluent is 2 years from the date of manufacture





Education Requirements

- FDA approved DoD Medication Guide
- DoD Smallpox Individual Trifold Brochure
- Shipped at no cost, same quantity as vaccine
 - Additional copies through MILVAX:
 - www.smallpox.mil/ACAM2000
 - www.vaccines.mil
 - vaccines@amedd.army.mil
 - 877-GET-VACC

Medication Guide

ACAM2000™

Smallpox (Vaccinia) Vaccine, Live

Please read this Medication Guide before you receive a vaccination with ACAM2000. This Guide does not take the place of talk with your healthcare provider about ACAM2000 and the smallpox vaccine.

What is the most important information I should know about the ACAM2000 smallpox vaccine?

If you are at a high risk for being exposed to smallpox, you should be vaccinated even if you have health problems, if you have certain problems with your immune system. People who have health problems may have a higher chance of getting serious side effects from vaccination but are also those who have a higher chance of dying from the smallpox disease.

ACAM2000 may cause serious heart problems called myocarditis and pericarditis, or swelling of the heart tissues. In studies, about 1 in every 175 persons who got the vaccine for the first time have experienced myocarditis and/or pericarditis. On rare occasions, these conditions can result in an irregular heart beat and death. The chances of getting heart problems from the vaccine are lower if you have already had this vaccine before. You can have myocarditis and pericarditis even if you have no symptoms.

Call your healthcare provider or get emergency help right away if you have:

- o chest pain or pressure
- o fast or irregular heartbeat
- o breathing problems

See "What are the possible side effects of ACAM2000?"

Because the vaccine has a live virus, it can spread to other parts of your body or to other people if you touch the vaccination site and then touch other parts of your body or other people. The virus can spread until the vaccination scab falls off (2 to 4 weeks after vaccination). If the virus is spread to a person who should not have the vaccine, the side effects can be very serious and life-threatening.


See "How do I care for the smallpox vaccination site?"

What is the ACAM2000 smallpox vaccine?

ACAM2000 is a prescription vaccine used to protect people against smallpox disease. It is for use in people who have a high chance of getting the disease.

ACAM2000 contains live vaccinia virus (a "pox"-type virus) against smallpox disease.

WHAT YOU NEED TO KNOW ABOUT SMALLPOX VACCINE



For more information visit
www.smallpox.mil
or
Contact us at:
vaccines@amedd.army.mil
877-GET-VACC
DSN 761-4245

1 August 2007

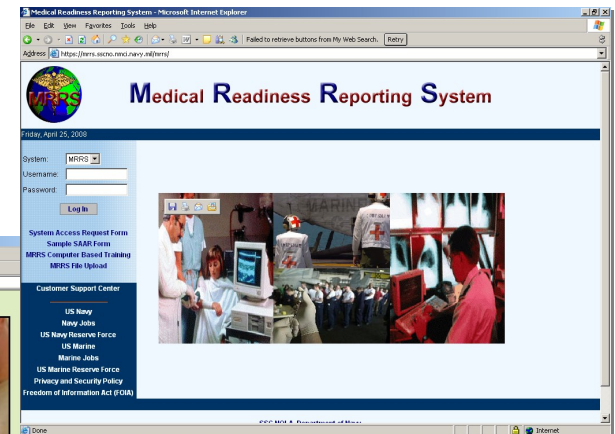
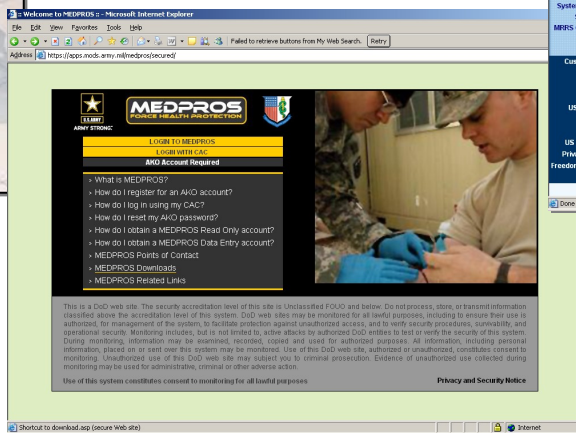
Local point of contact





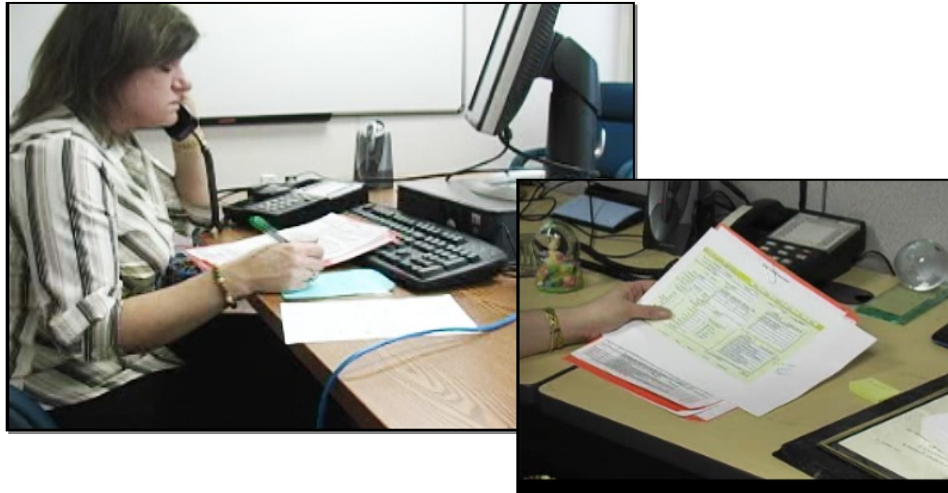
Immunization Record Keeping

- There is no change to the immunization record keeping requirements
- Every vaccination must be entered into a DoD approved electronic immunization tracking system





Ordering Information



- Orders for smallpox vaccine should be submitted through the US Army Medical Materiel Agency's (USAMMA) Distribution Operations Center (DOC) secure online order website
- Activities may request a registration form from USAMMA DOC
 - www.usamma.army.mil





Ordering Information (cont)

- When an order for Smallpox vaccine has been validated by the Service representative, USAMMA DOC will forward the request to the Centers for Disease Control and Prevention (CDC) Strategic National Stockpile (SNS)

- SNS will pack and ship smallpox vaccine, as directed by USAMMA DOC, to the requesting activity

NSN: 6505-01-559-0815

- NSN: 6505-01-559-0815, Smallpox (Vaccinia) Vaccine, Live with diluent, syringes, and needles

Lot # VV04-003A

Ensure that refrigerator
temps
are monitored twice daily

EVERY DAY

You should know

what actions

need to be taken when
the
temperature falls outside
the
proper range





Label



DoD uses the same FDA approved vaccine that is maintained in the Strategic National Stockpile, therefore all DoD stock will have the “**STRATEGIC NATIONAL STOCKPILE USE ONLY**” printed on its label. This vaccine is approved for use in the DoD.





Timeline

- 30 January 2008 Dryvax replaced with ACAM2000
- 29 February 2008 DoD clinics quarantine Dryvax
Activities continue with ACAM2000 vaccine
- 31 March 2008 suspense date for DoD Dryvax destruction
- During March, destruction paperwork must be forwarded to the USAMMA DOC
- Disposition instructions in MMQC 08-1072, 15 February 2008
Available at www.vaccines.mil or www.usamma.army.mil

USE ONLY ACAM2000 SMALLPOX VACCINE AFTER
01 MARCH 2008





Summary

- Remain alert to policy of program changes
- Appropriate training/competency documented
- ACAM2000 vaccine good for 30 days after reconstitution
- Latex-free stopper
- 15 JABS FOR ALL
- Adverse Events – vaccine developed using newer methods; cleaner product; clinical trials have seen comparable side effects with Dryvax and ACAM2000
- MILVAX Regional Analysts are available for assistance
- Contact MILVAX, VHC and USAMMA DOC for further guidance

MILVAX and USAMMA DOC web sites have the most current documents and information on ACAM2000





References available at www.smallpox.mil/acam2000

- Policy
 - Implementation Instructions, ACAM2000
 - Implementation Instructions, ACAM2000 MMQC-08-1036, 28 Jan 08
 - Disposition Instructions, Dryvax MMQC-08-1072, 15 Feb 08
- Staff Training
 - Package Insert ACAM2000
 - DoD Deployment Guidance ACAM2000
 - Healthcare Provider's Briefing and Service Messages
 - Dryvax/ACAM2000 Comparison Chart
 - Information Paper
 - Screening forms
 - Competencies
- Patient Education
 - DoD Medication Guide ACAM2000
 - Smallpox Vaccine Individual Trifold Brochure
 - Individual's Briefing and Service Messages





Information Sources

MILVAX Agency

- www.smallpox.mil; www.vaccines.mil/smallpox
- vaccines@amedd.army.mil
- 877.GET.VACC (877.438.8222)

DoD Vaccine Clinical Call Center

- 866.210.6469

DoD Vaccine Healthcare Centers

for help with complicated adverse-event management

- www.vhcinfo.org
- Askvhc@amedd.army.mil
- 202.782.0411

Information for Civilian Healthcare Providers

Call the Military Treatment Facility (MTF) where the member is enrolled

-OR- contact the Military Medical Support Office (MMSO)

- 888.647.6676 (if the member is not enrolled to an MTF)

Smallpox Vaccine in Pregnancy Registry

- NHRC-birthregistry@med.navy.mil
- 619.553.9255

USAMMA DOC

- www.usamma.army.mil
- 301.619.4318





www.vaccines.mil



www.vaccines.mil